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IN THE

Supreme Court of the United States

KSR INTERNATIONAL CO.,

Petitioner,

v.

TELEFLEX INC. AND TECHNOLOGY HOLDING CO.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether the Federal Circuit has erred in holding that a claimed invention cannot be held "obvious," and thus unpatentable under 35 U.S.C. § 103(a), in the absence of some proven "'teaching, suggestion, or motivation' that would have led a person of ordinary skill in the art to combine the relevant prior art teachings in the manner claimed."

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INTEREST OF AMICUS CURIAE[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. Member companies are in the business of developing new drugs—a complex process involving huge expenditures of time and money. In 2005 alone, PhRMA members invested an estimated $39.4 billion toward the discovery and development of new medicines. Collectively, PhRMA members are responsible for a huge portion of the innovative medicines approved for use in the United States in the past several decades.

Pharmaceutical companies spend many years working to develop each new drug that appears on the market, as well as many that will never earn approval. The process typically begins with creating a new compound or screening hundreds of thousands of existing compounds. The most promising compounds are then modified to optimize their properties, thus producing a candidate drug. At that point, both compounds and their potential uses are often separately patented. Selected compounds are then tested in the lab and in animals to determine whether they might effectively and safely treat a disease. That is followed by clinical trials in normal human volunteers and a series of studies in a relatively small number of patients. The next stage of development is a series of large clinical trials testing the effectiveness as well as the safety of a drug in patients. Those clinical trials, which typically take six to eight years, precede the

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[1] Counsel for both parties have consented to the filing of this brief, and the parties' letters of consent have been filed with the Clerk of Court. No counsel for any party authored this brief in whole or in part, and no person or entity, other than *PhRMA* or its members, contributed monetarily to the preparation or submission of this brief. A complete listing of PhRMA's members is available online at http://www.phrma.org/member_company_list/.

process of seeking approval from the Food and Drug Administration ("FDA"). Altogether, the entire drug development process might last upwards of fifteen years.

Moreover, a critical part of the research process is discovering how to deliver a drug substance to a patient in a safe and effective manner. That often involves creating appropriate dosage forms for delivery of the drug to a particular part of the body with certain specifications. Those dosage forms can be optimized with particular ingredients or coatings, and can involve combinations of ingredients or technologies designed to provide particular benefit to patients, exactly the kinds of innovations that could be affected by the outcome of this case. Such innovations can be significant for patient health.

Given the time and expense necessary to develop new drugs, intellectual property principles, especially those involving patent rights, are critical to PhRMA members and their research and development efforts. PhRMA has a strong interest in seeing the law continue to protect those patent rights essential to ensuring future innovation and the timely development of new medicines. As practitioners in an industry where research and development are expensive and competition is fierce, PhRMA's members need strong patent protection to be able to recoup the costs of their investments.

PhRMA submits that to show that a combination of prior art references renders a claimed invention obvious, within the meaning of 35 U.S.C. § 103(a), a challenger should have to provide evidence of either an express or an implicit motivation, suggestion, or teaching to combine the teachings of the references in the manner alleged to render the claimed invention as a whole obvious. Rejecting the requirement that the prior art show a motivation, suggestion, or teaching before finding a patent claim invalid under § 103 will make validity challenges unpredictable. The focus will shift from an objective analysis of what the prior art teaches to a person having ordinary skill in the art to a subjective analysis by the judicial officer considering the patent of

whether the claimed invention has sufficient merit to warrant a patent. Such an undesirable change in the law will significantly undermine the confidence of innovators such as PhRMA members in their ability to enforce patents against free-riding infringers who use the fruits of research and clinical-testing efforts of PhRMA members without incurring the costly expenses associated with developing, testing, and obtaining approval of new drug products. Hence, PhRMA members have a strong interest in preserving an obviousness standard that promotes predictability and uniformity in the obviousness analysis, to preserve the patent system as a strong economic driving force for highly beneficial, yet expensive, research and development efforts.

SUMMARY OF THE ARGUMENT

Through change in analytical perspective resulting from the enactment of § 103, patentability analysis now requires *objective* evidence that one of skill in the art would readily deduce a claimed combination from the prior art. Subjective assessment by the judiciary of whether the claimed subject matter meets the indefinable definition of "invention" has been repealed. It should not be effectively resurrected by permitting subjective conclusions or conclusory allegations of how one skilled in the art would use the prior art to govern an obviousness analysis concerning a claimed combination. Rather, the law should continue to demand that objective *evidence* be used in the analysis to show that, before the applicant's invention, one of ordinary skill in the art would have recognized that the prior art teachings could be combined as claimed in the patent. A lesser standard would lose sight of the congressional directive to consider the invention "as a whole." The evidence can be direct or circumstantial, i.e., an express or implicit motivation to combine the prior art teachings, but there must be evidence. That is what the "motivation-suggestion-teaching" ("MST") test does. It requires evidence to

support the contention that where all the components of a claimed invention are found individually in the prior art, one of skill in the art would find the claimed *combination*, when viewed "*as a whole*," obvious. There is no good reason to reject that test in favor of an unspecified standard that focuses the analysis on the differences between *individual* components of the claimed combination without demanding any objective evidence to ascertain whether the *combination* when considered as a whole would have been obvious as the statute explicitly requires. As Judge Rich explained, "*what* must have been obvious is '*the subject matter as a whole*.' . . . If, for example, a *combination* is claimed, Section 103 requires that to invalidate the claim, it must be shown that the *combination* was obvious, not merely its components." Giles S. Rich, *Laying the Ghost of the Invention Requirement*, 1 APLA Q.J. 26, 34 (1972), *reprinted in* 14 Fed. Cir. B.J. 163, 70 (2004) [*hereinafter* "Ghost"]. Rejecting the MST test will reintroduce subjectivity, hindsight, and uncertainty into patentability analysis, defeating the whole patent system and casting a cloud over many meritorious combination patents.

The arguments by the petitioner and its supporting amici—that the MST test requires an express teaching, precludes summary judgment, has no basis in this Court's precedents, and ill serves the patent law—do not withstand scrutiny. To the contrary, the test permits a wide variety of evidence, including implicit teachings and expert testimony, permits summary judgment when circumstances warrant, has support in this Court's pre- and post-§ 103 enactment precedents, and has beneficially served the patent law and advanced technology. Petitioner's contention that the Court should reject the MST test in favor of a standard that merely requires technical capability to combine the teachings of the prior art should not be adopted. It sets the bar too low, for it ignores the principle that a patentable invention can come from merely recognizing that a never-before-made combination can be made even if the combination is

simple—a principle this Court has long recognized and upheld. Neither should petitioner's suggestion that the Court resurrect a "synergy" requirement be adopted, since Congress overruled such a requirement with the enactment of § 103.

ARGUMENT

I. The "Motivation-Suggestion-Teaching" Test Should Remain a Requirement of an Obviousness Analysis

A. By Enacting § 103, Congress Sought to Inject Predictability, Uniformity, and Objectivity into Patentability Analysis

Determining whether a claimed invention comprised of components found in the prior art is patentable presents a question that "has taxed the ingenuity of courts ever since the passage of the patent acts." *C. & A. Potts & Co. v. Creager*, 155 U.S. 597, 606 (1895). To answer that question before the enactment of the 1952 Patent Act, courts examined the claimed subject matter to see whether it showed "invention" or the mere work of an ordinary mechanic. Focusing the analysis on whether the claimed subject matter showed sufficient "invention" proved unsatisfactory, as the answer often turned on the subjective views of the judicial officer considering the patent. That in turn led to inconsistency and unpredictability concerning whether a patent would be upheld or found invalid for lack of invention. *See* Rich, *Ghost*, 1 APLA Q.J.at 28-31, *reprinted in* 14 Fed. Cir. B.J. at 165-70.

To eliminate the subjectivity of the analysis and provide for uniformity in the application of the law, Congress enacted § 103 of the 1952 Patent Act.[2] Section 103 changed the focus of the analysis from whether the

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[2] S. Rep. No. 82-1979, at 6 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2400.

claimed subject matter showed a sufficient level of "invention" to whether the "differences between the subject matter sought to be patented and the prior art are such that the subject matter *as a whole* would have been *obvious* at the time the invention was made *to a person having ordinary skill in the art* to which said subject matter pertains." 35 U.S.C. § 103(a) (emphasis added). *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966). In other words, instead of judging whether the subject matter claimed in the patent rose to the dignity of "invention," a concept difficult to define, the analysis focuses on whether the claimed subject matter, when viewed as a whole, would have been "obvious" from the prior art to a person having ordinary skill in the art. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989) ("The nonobviousness requirement extends the field of unpatentable material beyond that which is known to the public under § 102, to include that which could readily be deduced from publicly available material by a person of ordinary skill in the pertinent field of endeavor.").

The late Judge Giles S. Rich, a principal drafter of § 103, instructed that the section was a legislative directive for a new approach to considering patentability. Rich, *Ghost*, 1 APLA Q.J. at 34, *reprinted in* 14 Fed. Cir. B.J. at 170 ("As compared to finding or not finding "invention," Section 103 was a whole new way of thinking and a clear *directive* to the courts to think that way. Some courts and some lawyers do not yet seem to realize that.").

Mr. P.J. Federico,[3] the other principal drafter of § 103,

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[3] Mr. Federico has been identified as the "primary author of the Patent Act of 1952" 75 J. PAT. & TRADEMARK OFF. SOC'Y 160, 160 (1993). *See also Paulik v. Rizkalla*, 760 F.2d 1270, 1277 (Fed. Cir. 1985) (Rich, J., *concurring*). Hence, although not definitive evidence of Congress's intent, *see In re Donaldson Co.*, 16 F.3d 1189, 1193 n.3 (Fed. Cir. 1994) (en banc) (Rich, J), his commentary provides useful

noted in his famous commentary that the drafters carefully chose the language of § 103 as a means of eliminating overly strict standards of patentability, laying the groundwork for an "attitude more favorable to patents," and stabilizing the law regarding patentability. According to Mr. Federico:

> There has been some discussion as to whether section 103 modifies the so-called standard of invention (which itself is an unmeasurable quantity having different meanings for different persons) in the courts and it may be correct to state that the printed record does not show an explicit positive command to the courts. While it is not believed that Congress intended any radical change in the level of invention or patentable novelty, nevertheless, it is believed that *some modification was intended in the direction of moderating the extreme degrees of strictness exhibited by a number of judicial opinions* over the past dozen or more years; that is, that some change of attitude *more favorable to patents was hoped for.* This *is indicated by the language used in section 103* as well as by the general tenor of remarks of Committees in the reports and particular comments. *Weight should be given to the terms used in the section* since a variety of expressions used in decisions were available, including some stated with an extreme degree of strictness, which could have been used as the model for the phraseology to be adopted, but the language selected was of the more moderate variety. The Committee Report, in the general part, states that the section "should have a stabilizing effect and minimize great departures

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information in understanding the policies the drafters sought to advance with the 1952 Act.

> which have appeared in some cases"; the departures of which complaint has been made in the recent past are all departures in the direction of greater strictness and hence these would be what the report indicates should be minimized.

P.J. FEDERICO, "COMMENTARY ON THE NEW PATENT ACT," 35 U.S.C.A. at pp. 22-23 (1954), *reprinted in* 75 J. PAT. & TRADEMARK OFF. SOC'Y 160, 183-84 (1993) (emphasis added). Mr. Federico also noted that after its enactment there were concerns that "new section 103 may not have the influence on the courts which was anticipated by its enactment." *Id.* at 23, *reprinted in* 75 J. Pat. & Trademark Soc'y at 184. That concern seems justified by the current positions urged by the petitioner and the amici supporting the petitioner.

B. The "Motivation-Suggestion-Teaching" Test Serves Four Important Purposes in Evaluating the Question of Obviousness Under the Framework of *Graham*

Section 103 of the Patent Act dictates that the main inquiry in considering the possible obviousness of a claimed invention is whether "the *differences* between the subject matter sought to be patented and the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a) (emphasis added). As guidance for conducting that analysis, this Court, in *Graham*, set forth the now familiar legal principle that

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

Graham, 383 U.S. at 17-18. While providing a starting point, the *Graham* instruction fails to provide explicit guidance on how one should apply the distinct evidentiary factors (a/k/a "the *Graham* factors") in determining obviousness. The MST standard provides an analytical framework, and perhaps the only possible analytical framework, for applying the *Graham* factors.

At least four important purposes in assessing the *Graham* factors are served by the MST test. First, by requiring evidence that one of skill in the art would have a motivation to combine the teachings of the prior art in a manner that yields the claimed invention, the standard ensures that the obviousness analysis gives due credence to the statutory requirement that the claimed invention be viewed "as a whole." Permitting the analysis to be based on the mere presence in various items of prior art of the elements of a claimed invention without requiring any showing that one of skill in the art would have been motivated to combine the teachings of those items of prior art risks transforming the analysis into a consideration of only the individual elements. But the statute demands that the invention be considered "as a whole."[4] Indeed, how can it accurately be proven that a claimed combination "as a whole" would have been obvious to a person having ordinary skill in the art without a showing that something would have taught, suggested, or

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[4] *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 959 (Fed. Cir. 1986); *see also Grain Processing Corp. v. Am. Maize-Prods., Co.*, 840 F.2d 902, 907-08 (Fed. Cir. 1988). *Cf. Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 344-45 (1961) ("the combination patent covers only the totality of the elements in the claim"); *Leeds & Catlin Co. v. Victor Talking Machine Co.*, 213 U.S. 325, 333 (1909) ("A combination is a composition of elements, some of which may be old and others new, or all old or all new. It is, however, the combination that is the invention, and is as much a unit in contemplation of law as a single or noncomposite instrument."), *overruled on other grounds sub nom. Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661 (1944), *superceded by statute* 35 U.S.C. § 271(d).

motivated that person to combine the teachings of the prior art in a manner to make the claimed combination?

Second, evidence of whether or not one of skill in the art would have had a motivation to combine the teachings of the prior art provides a way to evaluate the significance of the differences between the prior art and the claimed invention. Differences that may seem insignificant but would not have occurred to one of skill in the art likely deserve patent protection. Significant differences may not deserve patent protection if they would easily occur to one of skill in the art. Evidence showing the presence or absence of a motivation to combine the teachings of the prior art provides guidance for evaluating whether the differences between the claimed invention and prior art show that the invention would or would not have been obvious.

Third, requiring evidence that one of skill would be motivated to combine the teachings of the prior art to arrive at the claimed invention ensures that the fact-finder bases the obviousness determination on objective evidence of how one of skill in the art could view and use the prior art. Without that standard, fact-finders will rely on their own subjective perceptions of how one of skill in the art could use the prior art teachings. Reliance on subjective perceptions, rather than objective evidence, will lead to uncertainty in obviousness determinations, which in turn will create instability in the law.

Fourth, the MST test also serves "to guard against slipping into use of hindsight and to resist the temptation to read into the prior art the teachings of the invention in issue." *Graham*, 383 U.S. at 36.[5] Although the petitioner and several amici try to downplay the importance of

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[5] *See also Grain Processing Corp.*, 840 F.2d at 907 ("Care must be taken to avoid hindsight reconstruction by using 'the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.'").

guarding against hindsight, the need for that protection is especially important when a jury will determine the issue of obviousness.[6] Jurors on patent cases must often deal with new and complex technology that they have never encountered before. Over the course of a trial, which generally will last for at least several days, they are presented with testimony regarding the patent, the story of how the inventor created the invention, testimony on the prior art, a host of instructions on patent-law principles[7] and claim constructions to apply to the facts, demonstrative exhibits, usually conflicting testimony of highly qualified expert witnesses, and more. Given the overload of information, it is not realistic to expect a lay juror when determining the issue of obviousness to ignore the teachings of the patent specification when he or she must look to those teachings to understand and evaluate the invention for other purposes.[8] Requiring proof of a motivation to combine the teachings of the prior art to

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[6] Although obviousness presents a question of law, it is an issue typically given to the jury. *Adams v. Bellaire Stamping Co.*, 141 U.S. 539, 542 (1891); *Tucker v. Spalding*, 80 U.S. 453, 455 (1871); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1547 (Fed. Cir. 1983); *but see Shultz v. Moore*, 419 U.S. 930, 931-32 (1974) (Douglas, J., dissenting) (contending that validity questions should not go to a jury).

[7] *See, e.g.*, American Intellectual Property Law Association (AIPLA), "GUIDE TO MODEL PATENT JURY INSTRUCTIONS," Feb. 2006 (available at http://www.aipla.org/ Content/ ContentGroups/ Publications1/Publications_available_for_viewing1/ MPJ_021006.pdf) (providing 37 pages, in single-spaced type, of model jury instructions for use in a typical patent infringement case).

[8] For example, if a challenger to the patent asserts that the patent fails to enable a person of ordinary skill in the art to practice the invention or fails to provide an adequate written description of the claimed invention (both defenses arising under 35 U.S.C. § 112, para. 1), the juror must specifically consider the teachings of the patent specification. *See Permutit Co. v. Graver Corp.*, 284 U.S. 52, 59-60 (1931); *Expanded Metal Co. v. Bradford*, 214 U.S. 366, 380-81 (1909); *Wood v. Underhill*, 46 U.S.. 1, 4-5 (1847); *Pandrol USA, LP v. Airboss Ry. Prods., Inc.*, 424 F.3d 1161, 1165 (Fed. Cir. 2005); *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

arrive at the claimed invention helps to ensure that the jury does not impermissibly use the inventor's teachings in determining the obviousness or unobviousness of a claimed invention.

By achieving those four purposes, the MST standard realizes the congressional intent of stabilizing the patent law. The test provides an analytical framework that can be uniformly applied to all patent disputes. Furthermore, since it focuses on objective evidence of how one of skill in the art can use the teachings of the prior art, it avoids the unfairness and uncertainty of determinations based on subjective perceptions of the lay fact-finder. It also prevents the lay fact-finder from injecting into the obviousness analysis his or her perception of the worth of the patent.[9] And most importantly, it requires that the fact-finder consider only objective evidence, direct or circumstantial, of how one of skill could use the prior art teachings.

C. This Court's Precedents Support the "Motivation-Suggestion-Teaching" Test

The MST test has roots in the precedents of this Court. In determining patentability before the passage of the 1952 Patent Act, this Court often considered whether the prior art "suggested" the modification that yielded the claimed invention. For example, in *Topliff v. Topliff*, 145 U.S. 156, 161 (1892), the Court refused to find that a prior art patent, via a modification to its teachings, could invalidate an asserted patent where there was not "anything in [the prior art] patent which would have suggested [the modification] to a mechanic of ordinary intelligence, unless he were examining it for that purpose." The Court upheld the validity of a claim directed to an improved process for making expanded

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[9] Worth of patent is not, and should not be, the test for obviousness. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1573 (Fed. Cir. 1987).

sheet metal in *Expanded Metal Co. v. Bradford*, 214 U.S. 366, 381 (1909), because "the prior art does not suggest the combination of operations which is the merit of Golding's invention." In *Thomson Spot Welder Co. v. Ford Motor Co.*, 265 U.S. 445, 451, 453-54 (1924), the Court found "no error in law" in a lower court's analysis holding claims to a spot-welding process invalid for lack of invention where all the individual elements were known in the prior art and the combination was "naturally enough suggested by the prior art." Other case examples from the Court show that the notion that something other than the challenged patent must explicitly or implicitly suggest the claimed combination to a mechanic of ordinary skill has firmly been part of the patent law for well over a hundred twenty-five years.[10] Contrary to the contention of the petitioner and its supporting amici, the foregoing shows that this Court in the past has required the finding of an explicit or implicit suggestion in the prior art to combine the teachings of the prior art to yield the claimed combination before invalidating a combination claim.

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[10] *E.g.*, *Mast, Foos & Co. v. Stover Mfg. Co.*, 177 U.S. 485, 493-94 (1900) (claim to windmill gearing was held invalid because, in view of the state of the prior art, the claimed combination "would have been suggested to an intelligent mechanic, who had before him the patents to which we have called attention."); *Day v. Fair Haven & Westville Ry. Co.*, 132 U.S. 98, 102 (1889) (claim invalid where invention "would naturally suggest itself to any mechanic, and its use in that way is within the range of common knowledge and experience"); *Hollister v. Benedict & Burnham Mfg. Co.*, 113 U.S. 59, 72 (1885) (claim to a stamp device invalid since it was "the suggestion of that common experience, which arose spontaneously and by a necessity of human reasoning, in the minds of those who had become acquainted with the circumstances with which they had to deal"); *Tucker*, 80 U.S. at 455-56 (prior art reference should have been admitted if it "suggested to the mind of an ordinarily skilful mechanic" the claimed invention); *see also Peters v. Hanson*, 129 U.S. 541, 552-53 (1889) (noting expert testimony that an ordinary mechanic would be motivated to apply prior art teaching of using slots to provide adjustable attachments to invalidate claim).

This Court's § 103 precedents considering the validity of a claim in view of the combined teachings of prior art references show a continuing of the requirement that a challenger present evidence of an explicit or implicit motivation for one of skill in the art to combine those teachings in a manner that yields the claimed invention. For example, in *United States v. Adams*, 383 U.S. 39 (1966), the Court held the invention unobvious, in part, because the prior art "deter[red] any investigation into such a combination as is used by Adams." *Id.* at 52. In other words, the Court sustained validity because the prior art failed to show a motivation to combine the prior art teachings in a manner that yielded the claimed invention.

In *Calmar, Inc. v. Cook Chemical Co.*, the companion case to *Graham*, this Court effectively found an implicit motivation to combine teachings of prior art references where the references were directed to solving the same type of mechanical closure problem. 383 U.S. at 35. Similarly, *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969), shows another situation where the nature of the problem to be solved—in that case, preventing the formation of cold joints in paving operations—implicitly provided the necessary motivation to combine a radiant heat burner, known to be useful in eliminating cold joints, with a paving apparatus to yield the claimed invention.

Sakraida v. Ag Pro, Inc., 425 U.S. 273 (1976), provides an example where all the elements of the claimed combination were found in several prior art references directed to the same narrow field of the invention—systems using flowing water to clean animal wastes from barn floors. Hence, the narrow field of the invention provided the implicit motivation to combine the teachings of the references in a manner that yielded the claimed invention.

As shown in Section I(D), *infra*, all of those factors—the presence or absence of a suggestion in the prior art, nature of the problem to be solved, and narrow field of the invention—are factors the Federal Circuit considers as evidence that can be used to show a motivation for combining the teachings of the prior art.

D. The "Motivation-Suggestion-Teaching" Test Is Workable and Does Not Impose Undue Evidentiary Burdens

When Congress enacted § 103, it realized that additional criteria beyond the main standard in the statute would likely be needed to achieve the goal of providing a patentability analysis based on objective evidence and achieving greater uniformity in its conclusions.[11] The MST test is one of those "worked out" criteria.

In essence, the test requires merely that a conclusion of obviousness be based on objective *evidence*, and not a subjective judgment or conclusory assertions. The Federal Circuit made that clear in *Alza Corp. v. Mylan Laboratories, Inc.*, __ F.3d __, No. 06-1019, 2006 WL 2556356 (Fed. Cir. Sept. 6, 2006), where it explained:

> At its core, our anti-hindsight jurisprudence is a test that rests on the unremarkable premise that legal determinations of obviousness, as with such determinations generally, should be based on evidence rather than on mere speculation or conjecture. . . .
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> . . . [R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be *some* articulated reasoning with

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[11] Revision Notes to § 103 of Title 35, 1952 U.S.C.C.A.N. 2403, 2411 ("This paragraph [§ 103] is added with the view that an explicit statement in the statute may have some stabilizing effect, and also to serve as a basis *for the addition at a later time of some criteria which may be worked out*.") (emphasis added).)

> *some* rational underpinning to support the legal conclusion of obviousness. This requirement is as much rooted in the Administrative Procedure Act [for our review of Board determinations], which ensures due process and non-arbitrary decisionmaking, as it is in § 103.

Alza Corp., slip op. at 5-6, __ F.3d at __, 2006 WL 2556356, at *3-*4 (quoting *In re Kahn*, 441 F.3d 977, 989-90 (Fed. Cir. 2006)) (citations omitted).

This Court itself has noted that conclusory analysis and assertions are not sufficient for a patentability analysis. *Thomson Spot Welder*, 265 U.S. at 453 (rejecting invalidity analysis by one court that contained "only general allusions to the prior art and no analysis of the prior patents" while accepting invalidity analysis of a second court supported by factual findings).

The United States Patent and Trademark Office ("PTO") and those challenging the validity of a patent in court have a wide variety of *evidence* they can use to show that the prior art would motivate one of ordinary skill in the art to combine aspects of the prior art in a way that may render a claimed invention obvious. At one end of the spectrum, evidence that the prior art expressly discloses that the combination can be made will meet the standard.[12] At the other end of the spectrum, an implicit motivation to combine can also suffice.[13] Under Federal Circuit precedent, an implicit motivation to combine can be found where the prior art references are in the same

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[12] *E.g., In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004); *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1328 (Fed. Cir. 2004).

[13] *Alza Corp., slip op.* at 6, __ F.3d at __, 2006 WL 2556356, *4 ("There is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art. We do not have a rigid test that requires an actual teaching to combine before concluding that one of ordinary skill in the art would know to combine references."); *e.g., Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1341 (Fed. Cir. 2006) (implicit disclosure of interchangeability provided motivation).

field of invention.[14] The nature of the problem solved may also provide evidence of an implicit motivation where the prior art references address the same problem.[15] Nonconclusory expert testimony may also show that one of skill in the art would have been motivated to make the claimed combination.[16] Contrary to the contention of the petitioner and several amici, inherent knowledge of one of skill in the art (where that knowledge is articulated and placed in the record) can show the necessary motivation.[17] In fact, evidence used to show the motivation to combine does not even have to be publicly available.[18]

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[14] *E.g.*, *In re Johnston*, 435 F.3d 1381, 1384-85 (Fed. Cir. 2006); *In re Dance*, 160 F.3d 1339, 1343 (Fed. Cir. 1998).

[15] *E.g.*, *Old Town Canoe Co. v. Confluence Holdings Corp.*, 448 F.3d 1309, 1319 (Fed. Cir. 2006); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1322-23 (Fed. Cir. 2005); *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1339 (Fed. Cir. 2005); *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276-77 (Fed. Cir. 2004); *In re Inland Steel Co.*, 265 F.3d 1354, 1362 (Fed. Cir. 2001).

[16] *E.g.*, *Alza Corp.*, *slip op.* at 11-15, __ F.3d at __, 2006 WL 2556356, *6-*8; *Princeton Biochemicals, Inc.*, 411 F.3d at 1337-40; *Mazzari v. Rogan*, 323 F.3d 1000, 1005 (Fed. Cir. 2003).

[17] *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, *slip op.* at 20, __ F.3d __, __, No. 06-1088, 2006 WL 2806466, *11 (Fed. Cir. Oct. 3, 2006) ("Our suggestion test is in actuality quite flexible and not only permits, but *requires*, consideration of common knowledge and common sense."). *E.g.*, *Ormco Corp. v. Align Technology, Inc.*, *slip op.* at 16, __ F.3d __, __, No. 05-1426, 2006 WL 2493245, *7 (Fed. Cir. Aug. 30, 2006) (relying on "well-known practice of packaging items in the manner most convenient to the purchaser"); *Novo Nordisk A/S v. Becton Dickinson and Co.*, 304 F.3d 1216, 1219 (Fed. Cir. 2002); *see also In re Kahn*, 441 F.3d at 989-90.

[18] *Alza Corp.*, *slip op.* at 12, __ F.3d at __, 2006 WL 2556356, *7; *e.g.*, *Cross Med. Prods.*, 424 F.3d at 1322-23 (non-prior art material showed recognition of the problem to supply necessary motivation to combine or modify prior art teachings); *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd*, 357 F.3d 1319, 1337-39 (Fed. Cir. 2004) (motivation found from *unpublished* drawing made by an engineer and a private disclosure of a marketing employee to members of an engineering staff).

Additionally, under the Federal Circuit's precedents, evidence of a motivation to combine does not have to match the reasons contemplated by the inventor.[19] Given the wide variety of evidence, direct or circumstantial, that can be used to show a motivation, suggestion, or teaching to combine teachings of prior art references, the MST test does not place an undue burden on challengers or the PTO to substantiate a claim of obviousness with some form of objective evidence.[20]

Petitioner and several of the amici contend that the MST test virtually precludes summary judgment. That contention does not withstand scrutiny. The obviousness inquiry requires resolution of "factual inquires" before arriving at the ultimate legal conclusion on obviousness. *Graham*, 383 U.S. at 17. *But cf. Thomson Spot Welder*, 265 U.S. at 446 ("The question whether an improvement requires mere mechanical skill or the exercise of the faculty of invention, is one of fact."). Hence, where genuine issues of material fact exist regarding whether some form of objective evidence shows a motivation to combine teachings of references, it comes as no surprise that a district court may not grant summary judgment. *Fountain v. Filson*, 336 U.S. 681, 682-83 (1949). But

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[19] *E.g.*, *In re Fulton*, 391 F.3d at 1202; *In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992).

[20] The breadth of evidence that can be used to show an explicit or *implicit* motivation to combine teachings of the prior art refutes the characterization by some of the amici that the MST standard is nothing more than a "generalized novelty requirement." *See DyStar*, *slip op.* at 15-23, __ F.3d at __, 2006 WL 2806466, at *8-*12 (stating that commentators have distorted the "motivation-suggestion-teaching" test and illustrating cases showing the broad flexibility inherent in the test). The MST test also permits giving effect to the "ability to combine and modify prior art references that is consistent with the creativity and problem-solving skills that in fact are characteristics of those having ordinary skill in the art" as urged by other amici. *See id.*, *slip op.* at 26, 2006 WL 2806466, at *13. What the test does not permit, however, is conclusory assertions of a motivation to combine prior art teachings.

where the circumstances show no genuine issue of material fact on the question of obviousness, including whether a motivation exists to combine or modify prior art teachings, the Federal Circuit has affirmed invalidity rulings under § 103 on summary judgment.[21] Where proper the Federal Circuit has also affirmed summary judgments dismissing obviousness challenges.[22]

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[21] *E.g.*, *Rogers v. Desa Int'l Inc.*, No. 02-1247, 2006 WL 1965660 (Fed. Cir. July 13, 2006) (*nonprecedential*); *Athletic Alternatives, Inc. v. Benetton Trading USA, Inc.*, 74 Fed. Appx. 571, 574, No. 05-1378, 2006 WL 870806, *3 (Fed. Cir. Mar. 31, 2006) (*nonprecedential*), *cert. denied*, 2006 U.S. LEXIS 7222 (U.S. Oct. 2, 2006)); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004); *Mazzari*, 323 F.3d at 1005 (affirming summary judgment for PTO in a § 145 action); *Atl. Const. Fabrics, Inc. v. Dandy Prod., Inc.*, 64 Fed. Appx. 757, 762, No. 02-1451, 2003 WL 1949582, *4 (Fed. Cir. Apr. 23, 2003) (*nonprecedential*); *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1355 (Fed. Cir. 2001); *Gabrielidis v. Prince Sports Group, Inc.*, 243 F.3d 565, No. 99-1469, 99-1490, 2000 WL 1648134, *8-*11 (Fed. Cir. Nov. 1, 2000) (*nonprecedential*); *UV Coatings, Inc. v. Sico, Inc.*, 250 F.3d 763, No. 99-1336, 2000 WL 986965, *4-*5 (Fed. Cir. July 18, 2000) (*nonprecedential*); *Comfort Silkie Co. v. Seifert*, 215 F.3d 1344, No. 98-1476, 1999 WL 507166, *2 (Fed. Cir. July 16, 1999) (*nonprecedential*); *Select Engineered Sys., Inc. v. Sentex Sys., Inc.*, 194 F.3d 1331, No. 98-1166, 1999 WL 129637, *1 (Fed. Cir. Mar. 10, 1999) (*nonprecedential*); *Semmler v. Honda Motor Co.* 178 F.3d 1308, No. 97-1390, 1998 WL 791718, *4-*5 (Fed. Cir. Nov. 12, 1998) (*nonprecedential*); *Colvin v. Nat'l Auto. Parts Ass'n*, 168 F.3d 1321, No., 98-1104, 1998 WL 536885, *1 (Fed. Cir. Aug. 18, 1998) (*nonprecedential*); *Brand Mgt., Inc. v. Menard, Inc.*, 135 F.3d 776, No. 97-1329, 1998 WL 15241, *11 (Fed. Cir. Jan. 14, 1998) (*nonprecedential*); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 91 F.3d 169, No. 95-1320, 1996 WL 297601, *3-*4 (Fed. Cir. June 5, 1996) (*nonprecedential*); *Petersen Mfg. Co. v. Cent. Purchasing, Inc.*, 740 F.2d 1541 (Fed. Cir. 1984); *Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1577 (Fed. Cir. 1984); *Chore-Time Equip., Inc. v. Cumberland Corp.*, 713 F.2d 774, 778 (Fed. Cir. 1983).

[22] *E.g.*, *Crown Operations Int'l, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1378 (Fed. Cir. 2002); *Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1355 (Fed. Cir. 2001); *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus.*, 145 F.3d 1303, 1312-13 (Fed. Cir. 1998); *Kegel Co. v. AMF Bowling, Inc.*, 127

One of the amici supporting the petitioner suggests that the MST test unfairly prevents generic drug manufacturers from introducing generic forms of patented drug combinations. PhRMA submits that that observation does not withstand scrutiny either, for the Federal Circuit has invalidated drug-combination patents where the claimed drug combination was shown to be obvious under the MST test.[23]

Sound patent policy fostering predictability, uniformity, and stability in the patent law should not be sacrificed just so accused infringers or disenchanted licensees can summarily invalidate a patent. Hard-earned government rights, subject to a statutory presumption of validity,[24] should not be so easily cast

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F.3d 1420, 1430-31 (Fed. Cir. 1997); *Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1564 (Fed. Cir. 1988).

[23] *E.g.*, *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1370-71 (Fed. Cir. 2003); *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1484 (Fed. Cir. 1997).

[24] 35 U.S.C. § 282. This Court has held that one who seeks to invalidate a patent carries a "heavy burden of persuasion." *Smith v. Hall*, 301 U.S. 216, 233 (1937); *accord Mumm v. Jacob Decker & Sons*, 301 U.S. 168, 171 (1937); *Radio Corp. of Am. v. Radio Eng'g Labs., Inc.*, 293 U.S. 1, 7-8 (1934); *Adamson v. Gilliland*, 242 U.S. 350, 353 (1917). Petitioner and one of the amici contend that a "clear and convincing" evidentiary standard should not apply in an obviousness analysis. That question, however, is not within the scope of the Question Presented and should not be resolved in this case where the record and arguments are incomplete for that issue. Although petitioner and some amici contend that a lower evidentiary standard should apply when a challenger bases its obviousness analysis on prior art not considered by the PTO, neither considers the scenario of when that art is merely cumulative to art considered by the PTO. *See Otto v. Koppers Co.*, 246 F.2d 789, 801 (4th Cir. 1957) ("Astute and enterprising attorneys can always find [prior art] references not of record in the Patent Office, but if they do not involve some substantial element in the defense of anticipation [or obviousness] which was not considered by the Patent Office, the failure to make them record references cannot weaken the statutory presumption [of validity].").

down.[25]

E. Without the "Motivation-Suggestion-Teaching" Test There Are No Meaningful Guidelines for Objectively Analyzing Obviousness

It is notable that while criticizing the MST test, neither petitioner nor its supporting amici have offered alternative guidelines that permit an evaluation of obviousness based on objective evidence to show what one of skill in the art could or could not readily deduce from the prior art. Several amici suggest that the Court should reject the MST test and return to the *Graham* standard. But those amici have not offered any guidelines on how the differences between the claimed invention and the prior art should be assessed in view of the level of skill in the art to answer the statute's question: "Would the invention have been obvious?" The "no standard" approach amounts to an amorphous standard that will not achieve the congressional purposes of bringing stability and uniformity to the patent law. Furthermore, the parties urging the "return to *Graham*" fail to see that the MST test is nothing more than a rule of evidence for implementing the *Graham* standard. Others offer tests that effectively presume that anything that consists of a combination of items found in the prior art can be readily deduced by one of ordinary skill in the art. This Court has long rejected that premise, *see* Section II, *infra*, nor does that premise provide meaningful guidance for evaluating the *Graham* factors.

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[25] Parties seeking to challenge a patent have alternatives to litigation. Where a substantial new question of patentability exists, they can seek either an *ex parte* or an *inter partes* reexamination in the PTO. 35 U.S.C. § 301 *et seq.* Those proceedings are conducted within the PTO "with special dispatch." 35 U.S.C. §§ 305 & 314(c).

F. Petitioner's Anecdotal Evidence Does Not Show that the "Motivation-Suggestion-Teaching" Test Is a Failed Experiment

Members of this Court have wisely cautioned against imposing by judicial fiat overly strict patentability standards in reaction to random instances of patents of dubious validity. *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 572 (1949) (Jackson, J., *dissenting*). Petitioners and amici have offered several examples of anecdotal evidence purportedly showing patents of questionable validity upheld under a suspect application of the MST test, and sentiments of dissatisfaction with the current state of the patent system. That anecdotal evidence and self-interested promotion, however, fails to show that under the totality of the circumstances, the MST test has harmed or fails to beneficially advance the patent system. To the contrary, having the MST test has provided a robust patent system where obviousness challenges must be proven with objective evidence of how one skilled in the art would understand and use the teachings of the prior art rather than a subjective assessment by a judge or jury of whether the differences between the claimed invention and the prior art, considered individually, show the claimed invention would have been obvious. The MST test works especially well with complicated inventions. Concerns about possible mis-application of the test when applied to simple inventions do not lessen the need for the test or justify rejecting it. One cannot seriously question the rapid strides technology has made during the last twenty-four years under the carefully balanced incentive provided by the patent system's promise of limited exclusive rights. Upsetting that balance as the petitioner proposes risks crippling the pace of technology's advance.

II. THE STANDARD FOR DETERMINING OBVIOUSNESS SHOULD NOT BE MERE CAPABILITY OF COMBINING TEACHINGS OF REFERENCES

Petitioner suggests that instead of requiring evidence

of a motivation, suggestion, or teaching to combine the teachings of the prior art, the test should require only that one of skill in the art have the capability to make the combination. That test sets the bar too low.

As the late Chief Judge Markey stated, "Only God works from nothing. Men must work with old elements." *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 n.3 (Fed. Cir. 1985) (quoting Markey, J., *Why Not the Statute*, 65 J. Pat. Off. Soc'y 331, 334 (1983)). Accordingly, patentability is not, and never has been, denied merely because all elements of a combination are individually known in the prior art.[26] As this Court noted, if the rule were otherwise for combination patents "not one patent of the kind in a thousand of modern date could be held valid." *Parks v. Booth*, 102 U.S. 96, 104 (1880).[27]

Merely requiring that one of skill in the art have the capability to combine the teachings of the prior art references fails to give any consideration to whether one of skill in the art would, without the patent, know to do so. The merits of an invention can lie in just recognizing that the claimed combination can be made even though in hindsight the invention was simple and its making well within the capability of one of skill in the art.[28]

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[26] *Cantrell v. Wallick*, 117 U.S. 689, 694 (1886) (rejecting "theory that a patent cannot be valid unless it is new in all its elements as well as in the combination, if it is for a combination" because "no patent for an improvement on a known contrivance or process could be valid" under that theory (citations omitted)); *Parks*, 102 U.S. at 102; *Gould v. Rees*, 82 U.S. 187, 189 (1872); *Seymour v. Osborne*, 78 U.S. 516, 542 (1870); *see also Imhaeuser v. Buerk*, 101 U.S. 647, 660 (1879).

[27] *Accord Panduit Corp.*, 810 F.2d at 1575 ("The notion ... that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, § 103."); *Connell*, 722 F.2d at 1549.

[28] The poet Milton described that phenomenon over three centuries ago: "The invention all admired, and each how he To be the inventor missed; so easy it seemed, Once found, which yet unfound most would have thought, Impossible!" *Paradise Lost*, Part VI, L. 478-501 (*quoted*

Acknowledging that, and the consequent need to consider whether the combination would have *occurred* to one of skill in the art, this Court has explained:

> [I]t often requires as acute a perception of the relation between cause and effect, and as much of the peculiar intuitive genius which is a characteristic of great inventors, to grasp the idea that a device used in one art may be made available in another, as would be necessary to create the device *de novo*. And this is not the less true if, after the thing has been done, it appears to the ordinary mind so simple as to excite wonder that it was not thought of before. The apparent simplicity of a new device often leads an inexperienced person to think that it would have occurred to any one familiar with the subject; but the decisive answer is that with dozens and perhaps hundreds of others laboring in the same field, it had never occurred to any one before. The practiced eye of an ordinary mechanic may be safely trusted to see what ought to be apparent to every one. . . .
>
> As a result of the authorities upon this subject, it may be said that, if the new use be so nearly analogous to the former one that the applicability of the device to its new use would occur to a person of ordinary mechanical skill, it is only a case of double use; but if the relations between them be remote, and especially if the use of the old device produce a new result, it may at least involve an exercise of the inventive faculty.

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in Gillette Co. v. S.C. Johnson & Son, Inc., 919 F.2d 720, 726 (Fed. Cir. 1990)).

C. & A. Potts & Co., 155 U.S. at 607-08.[29]

Petitioner's suggested test of merely determining whether one of skill in the art would have the capability to make the claimed combination—without considering whether there is any evidence to show that one of skill would have had the motivation to make the combination—fails to consider the standard pronounced in *C. & A. Potts* of whether the combination "would occur to a person of ordinary mechanical skill." It also fails to heed the statute's command that the invention must be viewed as a "whole." A necessary component of the "whole" is knowing that elements can be combined to create the "whole." The capability of physically combining items or teachings in the prior art does not show that one of skill in the art would have recognized that the "whole" could even have been made from the prior art.[30]

The alternative test suggested by one of the amici of applying a rebuttable presumption that one of skill in the art would be motivated to combine the teachings of the prior art where the references are analogous art also fails to consider whether the thought of the combination would occur to one of skill in the art. It erroneously presumes that the thought would be there. Accordingly, it suffers the same deficiencies as the petitioner's proposed test and should not be adopted.

The Federal Circuit recently suggested in *DyStar* that

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[29] *See also Diamond Rubber Co. v. Consolidated Rubber Tire Co.*, 220 U.S. 428, 434-35 (1911); *Barbed Wire Patent*, 143 U.S. 275, 282-83 (1892).

[30] *E.g.*, *Hobbs v. Beach*, 180 U.S. 383, 393 (1901) ("the mere change in shape of the dies was a minor part of the work . . . the invention consisting rather *in the idea* that such change could be made, than in making the necessary mechanical alterations") (emphasis added); *Loom Co. v. Higgins*, 105 U.S. 580, 591 (1881) ("Now that [the inventor] has succeeded, it may seem very plain to any one that he could have done it as well. This is often the case with inventions of the greatest merit."); *see also Panduit Corp.*, 810 F.2d at 1572 ("The statute requires utility, novelty and nonobviousness, not complexity.").

the capability of one of ordinary skill to combine teachings of prior art references occasionally may supply the requisite motivation to combine. *DyStar*, *slip op.* at 21, __ F.3d at __, 2006 WL 2806466, at *11. Importantly, however, the court qualified its statement with a companion requirement for a presence of a technology-independent economic driving force motivating one of skill in the art to seek a product or process that could be "stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient." *Id.* In that context—economic motivation for a product or process having certain improved advantages plus technical capability to modify the technology to achieve the advantage—it can, in many circumstances, make sense to find an implicit motivation to combine teachings of prior art references in a way that will obviously realize the sought after advantage. Absent the economic driving force, it would not make sense to presume that just because one of skill in the art had the technical capability to combine the teachings of the prior art, he or she would have thought to do so. Hence, the Federal Circuit's statement in *DyStar* should not be viewed as endorsing the petitioner's suggested test that mere capability, even in the absence of a technology-independent economic driving force, suffices to prove that it would have been obvious to combine teachings of prior art references.

III. SYNERGY SHOULD NOT BE THE TEST FOR HOLDING A COMBINATION PATENT VALID

The petitioner and some of the amici supporting the petitioner suggest that statements in *Sakraida*, 425 U.S. at 282, and *Anderson's-Black Rock, Inc.*, 396 U.S. at 61, noting the absence of a "synergistic effect" in the claimed invention, should apply as a special definitive test for determining validity of combination patents. Imposing a requirement of synergy is not warranted and would virtually destroy the patent system.

A. The Text of § 103 Does Not Support a Synergy Requirement

The plain language of § 103 shows that an analysis for obviousness must focus on the "*differences* between the subject matter sought to be patented and the prior art" to determine whether "the subject matter as a whole *would have been obvious* at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a) (emphasis added). Notably, the statute does not say that the "differences" between the subject matter sought to be patented and the prior art must include a new result produced by the claimed invention. Nor does it state that to be unobvious the subject matter must produce a new result. Accordingly, the deliberate[31] absence of a "new result" requirement in the text of § 103 strongly suggests that one should not be read into the statute.[32] *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 454 (2002) (refusing to

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[31] One of the principal drafters of § 103 stated: "Weight should be given to the terms used in the section since a variety of expressions used in decisions were available, including some stated with an extreme degree of strictness, which could have been used as the model for the phraseology to be adopted, but the language selected was of the more moderate variety." FEDERICO, "COMMENTARY ON THE NEW PATENT ACT" at 23, *reprinted in* 75 J. PAT. & TRADEMARK OFF. SOC'Y at 183.

[32] Many things can be unobviously different, but produce the same result. Indeed, this is why in analyzing infringement under the doctrine of equivalents this Court has required a showing that the same *function* is performed in the same *way* to achieve the same *result*, and rejected contentions that infringement should be found where only the same result is achieved. *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 608 (1950); *Weber Elec. Co. v. E.H. Freeman Elec. Co.*, 256 U.S. 668, 675 (1921). Given the relationship between validity and infringement as exemplified by the maxim "that which [literally] infringes if later, anticipates if earlier," *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889), a principle that infringement cannot be found merely because the same result is achieved suggests that invalidity should not be found merely because the same result is achieved.

read into statute provisions that Congress could have "clearly and explicitly" included but did not); *Bradley v. Richmond Sch. Bd.*, 416 U.S. 696, 716 n. 23 (1974) ("We are reluctant to read into the statute the very ... limitation that Congress eliminated."); *see also Park 'N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 (1985) ("Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose.").

Furthermore, the Patent Act requires a "new and useful" criterion as a condition for patentability under only the utility requirement of 35 U.S.C. § 101,[33] a patentability requirement separate and distinct from unobviousness under § 103. *Diamond v. Diehr*, 450 U.S. 175, 191 (1981). Under traditional rules of statutory construction, where Congress has included a requirement in one statutory provision and omitted it in another, it is to be presumed that the omission was intentional. *Barnhart*, 534 U.S. at 452. Hence, the presence of a "new and useful" requirement in § 101 counsels against construing § 103 to include a requirement that a combination patent must provide a synergistic effect.

B. A Synergy Requirement Is Contrary to the Legislative Purpose of § 103

The legislative history of § 103 does not expressly state that the changes made by the statute legislatively overruled a synergy requirement. But one of the principal authors of the statute has stated that that was the intent of § 103. Addressing how the reasoning of the majority and concurring opinions in *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147 (1950), prompted the drafting committee to develop a new

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[33] 35 U.S.C. § 101 limits patentable subject matter to a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . ."

standard for determining patentability to replace the "invention" standard, Judge Rich commented that "what was said in the opinions [was] typical of all that was wrong with the patent law's 'invention' requirement." Rich, *Ghost,,* 1 APLA Q.J. at 32, *reprinted in* 14 Fed. Cir. B.J. at 168-69.

Judge Rich explained that the new patentability standard provided in § 103 overruled *Great A & P* to the extent that case required that special rules, such as synergy, apply to combination patents.[34] With § 103, the drafters intended to establish a uniform standard applicable to all classes of invention without requiring synergy. *Id.* at 32-33, *reprinted in* 14 Fed. Cir. B.J. at 169-70.

Addressing the apparent resurgence of a synergy requirement based on dictum in *Anderson's-Black Rock, Inc.*, 396 U.S. 57, Judge Rich again noted that synergy is "an impossible test, so Section 103 was enacted to replace it." He stated:

> Now what was the dictum in *Black Rock* that bugs people? Well, it was the very idea expressed in *A & P* which stimulated the enactment of Section 103 to supplant it, but which, unhappily, is still current dogma in some courts, namely, that inventions which are a combination of old elements must be tested for patentability (formerly for "invention" now for unobviousness) by an extra severe test—more severe than the test for inventions of other kinds. *A & P* spoke of the "difficulty and improbability of finding invention in an assembly of old elements" and said the whole must in some way exceed the sum of its parts to produce unusual or surprising consequences. That

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[34] *See also* P.J. Federico, *Origins of Section 103*, 5 APLA Q.J. 87, 95 (1977) (the *Great A & P* case "served to stimulate" the committee meetings that resulted in the new patentability standard of § 103).

> is the "severe test." It was indeed severe—it was an impossible test, so Section 103 was enacted to replace it.
>
> . . . .
>
> Congress in Section 103 threw down the gauntlet to these notions by substituting a different test—the obviousness test—applicable to all inventions alike. Since then no justification can be found for treating one kind of invention differently from another.
>
> . . . .
>
> . . . I doubt that any trial lawyer, ever, is going to be able to meet the "strict test" implicit in the following two unfortunate sentences of the *Black Rock* dictum:
>
> > A combination of elements may result in an effect greater than the sum of the several effects taken separately. No such synergistic result is argued here.
>
> The laws of physics and chemistry in accordance with which all inventions perform do not permit of the judicially imagined magic according to which 2 + 2 = 5. Wherever such a spurious test prevails all patents are invalid. And there are those who think that is heaven.

Rich, *Ghost,* 1 APLA Q.J. at 43-44, *reprinted in* 14 Fed. Cir. B.J. at 177-78.

Given that a synergy requirement presents an almost impossible requirement to meet, has no basis in the text of § 103, and was intended to be eliminated by the enactment of § 103, it should not be adopted.

CONCLUSION

For all the above reasons, the use of the MST test should be upheld.

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